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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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NEW YORK NY 10112

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EXAMINER

OSTRUP, C

ART UNIT	PAPER NUMBER
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1619

DATE MAILED:

8
06/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/719,662

Applicant(s)

ABRAM, ALBERT ZORKO

Examiner

Clinton Ostrup

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 3 and 7 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claims 1-18 are pending in this application.

Priority

Priority to Australian Application Number PP 5831, filed September 11, 1998, is acknowledged. Further, priority to PCT/AU99/00735 filed September 8, 1999.

Specification

The disclosure is objected to because of the following informalities:

- Page 2, line 15, it appears there is an inadvertent period between the word "in" and "both".
- Page 3, line 2 it is not necessary to have a comma after the word "of."
- Page 3, line 22 the word utilized is misspelled as "utilised."

Appropriate correction is required.

Claim Objections

Claim 3 is objected to because of the following informalities: the commas after "of" and "valerate" are not necessary. The addition of these commas makes the claim difficult to understand. The examiner respectfully suggests eliminating these commas.

Claim 7 is objected to because of the following informalities: it appears there was an inadvertent underscore after the word "weight."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 recites the limitation ^{the} "pharmaceutical mousse composition." However, there is insufficient antecedent basis for this limitation in the claim. Claim 1 from which this claim 4 depends describes a pharmaceutical aerosol foam composition and the examiner urges applicant to be consistent with their terminology.

The term "long" in claim 5 is a relative term, which renders the claim indefinite. The term "long" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 6 is vague and indefinite because the term "includes" is open language. However, claim 5 from which claim 6 depends, uses the terminology "consisting of," which is closed language. Therefore, it is

unclear how an occlusive agent can consist of one or more of the specific ingredients of claim 5, and then include petrolatum as well as other ingredients.

Claim 9 is vague and indefinite because it includes an effective amount of an emulsifier and/or surfactant, but it is unclear what the emulsifier and/or surfactant is effective for.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-11, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Breton et al. **5,733,558**. Breton et al. disclose a method for the treatment of acne and/or the effects of aging on the skin. See: abstract and col. 1, lines 8-16. Breton et al. describe a composition containing HMG-CoA-reductase (a rate-limiting enzyme in the biosynthesis of cholesterol) inhibitors and other active agents in amounts which encompass those of instant claim 4. See: col. 1 lines 6-63.

The reference describes using a topical composition which is preferably in aqueous, aqueous-alcoholic or oily solutions. Breton et al. describe these solutions as optionally being in aerosol form and specifically describes them as creams, milks, lotions, gels or foams for the face, hands, body, or for cleansing skin. The reference describes these aerosol compositions as containing a dermatologically acceptable propellant, under pressure, and the means of making these compositions as conventional. See: col. 4, lines 20-45.

Breton et al. describe using the pharmaceutical active ingredients of instant claims 2-3, the specific occlusive agents of instant claims 5-6, and the emulsifiers of instant claims 9-11. See: col. 5, line 15 – col. 6, line 16. Breton et al. describes emulsifiers as comprising 0.3% to 30% of the total weight of the composition, thus meeting the specific limitation of claim 12. See: col. 4, lines 56-68. Further, the reference describes a fatty phase which can contain as little as 5% and as much as 90% of the total weight of the composition, depending on the specific form of the composition desired. See: col. 4, line 50 – col. 5, line 14.

Breton et al. also describe the compositions as being water-in-oil or oil-in-water emulsion and describe suitable adjuvants such as solvents,

which comprise 0.01%-20% of the total composition. See: col. 5, lines 4-14. The reference further describes suitable solvents, which may be used and describes these solvents as lower alcohols such as ethanol, isopropanol, and glycols such as propylene glycol. See: col. 4, lines 32-40 and col. 5, lines 29-54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton et al. **5,733,558** as applied to claims 1-6, 9-11, 16, and 18 above, and further in view of Gers-Barlag et al. **5,833,960**.

The Breton et al. reference teaches a skin treatment composition as described above, however, this reference does not specifically teach the amounts of aqueous solvent or propellant as claimed instantly by claims 13 and 17, respectively. Further, the primary reference does not teach the organic solvent of instant claims 15.

Gers-Barlag et al. describe foaming, light protection preparations and a method of using them to protect skin from harmful wavelengths of light. See: abstract and col. 12, line 37- col. 13, line 11. Foams, according to the secondary reference, allow a fine distribution of substances onto the skin. See: col. 9, lines 3-28. The secondary reference describes the oil phase as comprising 1%-50% by weight of the preparation. See: col. 15, lines 24-27. The secondary reference describes mixtures of C₁₂₋₁₅ -alkyl benzoates, the specific organic solvent of claim 15, and other compounds as particularly advantageous in the oil phase. See: col. 14, line 60 – col. 15 line 5.

The secondary reference teaches the use of aerosol container and an amount of 5.00% by weight of a propellant (butane/isobutane/propane). Thus, meeting the specific limitations of claim 17. See: col. 16, Example 3. Further, the reference teaches the addition of water to an aqueous phase to make the composition have a sum total of 100.00% by weight. The amount of water added to the formulation meets the specific limitations of claim 13. See: col. 15, line 28 - col. 16, line 68.

Gers-Barlag et al. further describe less soluble components in the formulation as having better spreadability than in formulations known in the art. See: col. 9, lines 9-14. The secondary reference describes the

formulation as having "particularly good skin compatibility, making it possible to spread valuable ingredients particularly well on the skin." See: col. 9, lines 15-29.

It would have been obvious to one having ordinary skill in the art, at the time the invention was made, to have modified the skin treatment composition of Breton et al. by adding the amounts of aqueous solvent and propellant as well as the alkyl benzoates as taught by Gers-Barlag et al. because of the expectation of obtaining an aerosol foam skin treatment composition which provides good skin compatibility and makes it possible to spread valuable, less soluble ingredients particularly well on the skin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1619

June 13, 2001


DANA DUDASH
SUPERVISORY PATENT EXAMINER
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